

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 51-F-0019
CUSTOMER NUMBER: 452

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Us Army Edgewood Chemical Biological Ctr
Bldg E3150 Attn: Amsrd-Ecb-Rt-Tv
Aberdeen Prove Grnd, MD 21010

Telephone: (b)(6), (b)(7)c

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A.	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reason such drugs were not used must be attached to this report)	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		2	10	94	106
7. Hamsters					
8. Rabbits		264	15	164	443
9. Non-human Primates					
10. Sheep					
11. Pigs		0	0	144	144
12. Other Farm Animals					
13. Other Animals					
Rats		8	274	147	429

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(b)(6), (b)(7)c

S

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(Type or Print)

DATE SIGNED

1 Dec 08

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Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 51-F-0019

2. Number 94 (guinea pigs) / 54 (rats) of animals used in this study.

3. Species (common name) guinea pigs/rats of animals used in the study.

4. Explain the procedure producing pain and/or distress.

Ninety-Four (94) guinea pigs and fifty-four (54) rats were used to test militarily unique compounds via the inhalation route to establish relative importance of exposure concentration and duration on the probability of toxic and lethal responses. Historically, in studies designed to generate lethal dose-response curves, it has been assumed that approximately half of the exposed animals would be expected to die and that this level of response may potentially be associated with pain, discomfort, and/or distress.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below)

For these studies, the use of anesthetic/analgesic drugs during exposure may compromise the results of the proposed studies due to the fact that this class of compound may alter the respiratory minute volume and thus the dose of test compound that the animal receives. In addition, the expression of toxic signs may be altered by such treatment. Clement and Coperman (1984) suggest that chemical agent-induced convulsion and death are not necessarily associated with pain.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency _____ CFR _____

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1. Registration Number: 51-F-0019

2. Number 54 (rats) of animals used in this study.

3. Species (common name) rats of animals used in the study.

4. Explain the procedure producing pain and/or distress.

Fifty-four (54) rats were tested with previously untested chemicals of military interest. The materials were tested by subcutaneous route.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

It is unknown as to whether or not a subcutaneous exposure to VX causes pain, Therefore, no analgesics are required. Furthermore, the use of anesthetic or analgesic compounds may result in metabolic byproducts that may interfere with, or produce artifacts in the data.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency _____ CFR _____

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1. Registration Number: 51-F-0019

2. Number 164 (rabbits) / 144 (swine) of animals used in this study.

3. Species (common name) rabbits/swine of animals used in the study.

4. Explain the procedure producing pain and/or distress.

One hundred sixty-four (164) rabbits and one hundred forty-four (144) swine were tested with previously untested chemicals of military interest. The materials were tested by dermal route.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

Animals that either died or suffered convulsive seizures during the test – these severe toxic signs could not be alleviated so that accurate test data could be collected. The data collected were important for several reasons: 1) to establish the toxicological profile of the chemical; 2) to establish data to be used for human estimates; 3) to establish data from which therapy/prophylaxis could be established; and 4) data would be included in material safety data sheets as a warning to potential users or in support to chemical staff in case of accidental exposures.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency _____ CFR _____

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1. Registration Number: 51-F-0019

2. Number 39 (rats) of animals used in this study.

3. Species (common name) rats of animals used in the study.

4. Explain the procedure producing pain and/or distress.

Thirty-nine (39) rats were tested with previously untested chemicals of military interest. The materials were tested by intratracheal route.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

The rats will be exposed to procedures, which can potentially cause them distress. At doses that result in toxic effects (gasping, bronchoconstriction), pain may develop during or after exposure resulting from an injury or stress/irritation of tissues. Toxic signs are expected to be relatively mild. While these should not be painful, they could cause some degree of distress. Pre-treating the animals with analgesics is not an option because it could potentially affect the BAL, or pathology results.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency _____ CFR _____